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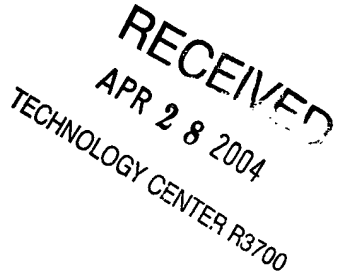
A.F/3761

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	SPRUIELL	Examiner:	MENDOZA, MICHAEL G
Serial No.:	10/075,088	Art Unit:	3761
Filed:	2/16/02	Dkt. No.:	IMA-0014-OXYPAK

Title: PATIENT USABLE EMERGENCY MEDICAL KIT

APPELLANT'S REPLY BRIEF UNDER 37 C.F.R. § 1.193



Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

In compliance with 37 C.F.R. § 1.193 this Reply Brief is being filed within two months of the date of the Examiner's Answer, mailed on 2/24/04. No fee is believed necessary; however, should a fee be required it will be timely paid upon written notice from the Office.

Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as FIRST CLASS MAIL in an envelope addressed to: Commissioner of Patents PO Box 1450 Alexandria VA 22313-1450 on the date listed below.

Name: Edward L. Kelley Signature: Edward L. Kelley Date: April 23, 2004

Reg. No.: 41, 112

1) REAL PARTY IN INTEREST:

As stated in the Appellant's Brief

2) RELATED APPEALS AND INTERFERENCES: In the Examiner's Answer, the Examiner stated, "the brief, does not contain a statement identifying the related appeals and interferences." However, Appellant's brief clearly states; "there are no related appeals or interferences."

3) STATUS OF THE CLAIMS:

As stated in the Appellant's Brief.

4) STATUS OF THE AMENDMENTS:

No amendment after final has been filed.

5) SUMMARY OF THE INVENTION

As stated in the Appellant's Brief.

6) ISSUES

As stated in the Appellant's Brief.

7) **GROUPING OF THE CLAIMS**

As stated in the Appellant's Brief.

8) ARGUMENT

Appellant argued that the rejection of claims 5, 7 and 14 - 16 under 35 U.S.C. §102 (b) as being anticipated by Anderson 4,197,842 is improper, based on *Verdgaal Bros. v Inion Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); because Anderson fails to teach the claim limitations of; in clam 7;

"a breathable oxygen delivery system and a medication for use in response to symptoms

of an attack of a vascular disease"

or; in claim 14,

"*a breathable oxygen delivery system and a medication for one of, assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and, assisting in diminishing oxygen demand.*"

With respect to claim 7 the Examiner argues that the limitation; "*the medication is for use in response to symptoms of an attack of a vascular disease,* is functional language and is not given any patentable weight. The limitations must result in a structural difference. Therefore, the system of Anderson is fully capable of delivering the medication as described."

With respect to claim 14, the Examiner mischaracterizes the limitations set out in claim 14, but applies the same argument.

Appellant submits that the Examiner's assertion that the medication use is functional language and therefore not given any patentable weight, and further that the limitations must result in a structure difference, constitute new grounds for rejection. These arguments are asserted for the first time in the Examiners Answer. The Examiner has heretofore merely stated that the system of Anderson is fully capable of delivering the medication as described. Furthermore, Appellant's claims do not rely on any apparatus to deliver the medication. The medication set out in Appellants claims is merely included in the medical kit. The medication itself is the structure. Therefore, the Examiner's statement that Anderson is fully capable of delivering the medication is completely irrelevant to claims 7 or 14.

Applying new grounds for rejection is prohibited in an Examiners Answer under 1.193 (a) 2. The Examiners Answer constitutes new grounds for rejection, because it is respectfully submitted that the basic thrust of the rejection is changed and that the Appellant has never been given a fair opportunity to react to the assertion that the medication use is functional language and therefore not given any patentable weight. It is respectfully submitted that new grounds for rejection submitted in the Examiner's

Answer should not be considered on appeal.

However, should these new ground be considered, Appellant refers to MPEP 2173.05(g); "A functional limitation must be evaluated and consider, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." See also *In re Barr*, 444 F.2d 588, 170 USPQ 33 (CCPA 1971) which held, "a functional limitation was perfectly acceptable because it sets definite boundaries on the patent protection sought."

Appellant respectfully submits that claims 7 and 14 fairly convey to a person of ordinary skill in the art that an emergency medical kit comprising breathable oxygen and a *medication for use in response to symptoms of an attack of a vascular disease* or *a medication for one of, assisting in preventing thrombosis, assisting in inducing arteriolar relaxation, assisting in establishing a cardiac rhythm, and, assisting in diminishing oxygen demand* sets out definite boundaries on the patent protection sought and moreover, that there is no confusion that claims 7 and 14 are different from the teachings of Anderson.

The Examiner has previously stated; "Anderson teaches an emergency medical kit, comprising a breathable oxygen delivery system and a medication, the system being fully capable for use in response to symptoms of an attack of a vascular disease; a portable container; wherein the medication is prescribed for a particular user by a physician." (Page 2, paragraph 3, Office action mailed 6/24/03).

Appellant maintains that neither this argument nor the new argument, that functional limitations have not been given patentable weight, do not address Applicant's position that, each of the elements set forth in claims 7 and 14 is not described in Anderson, either expressly or inherently, because Anderson fails to teach a medication for treating a vascular disease. The medication required by claims 7 and 14 is a structural element of the medical kit. The limitations set out in claims 7 and 14 serve to precisely define structural attributes of the emergency medical kit, including which medications are available for treating a vascular disease, as set forth in Appellants' specification. See *In*

re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) which held that functional limitations "served to precisely define present structural attributes of interrelated component parts of the claimed assembly."

In addition, claims 7 and 14 include other structural differences that further distinguish them over the teachings of Anderson. In particular, Anderson teaches a mode called Intermittent Positive Pressure Breathing, (I.P.P.B.), wherein a mixture of air, oxygen and medication is delivery to the patient through a nebulizer assembly. Claims 7 and 14 do not set out a nebulizer assembly. The I.P.P.B. mode of Anderson requires an electric powered blower that pushes a medicinal mist into the patient's airways, (Col. 1, lines 35 - 42 and Col. 3, lines 5 - 6). Claims 7 and 14 do not set out an electric powered blower, a medicinal mist, or any apparatus for pushing medication into the airways of the patient. Anderson teaches delivering pure oxygen to the patient through a breathable facemask, but only with the medication-delivering nebulizer assembly removed. (Col. 3, lines 11 - 15). Appellant's emergency medical kit of claims 7 and 14 requires a breathable oxygen delivery system in combination with a medication for treating vascular disease. Anderson neither expressly nor inherently teaches an emergency medical kit combining a breathable oxygen delivery system with a medication for treating a vascular disease. Moreover, Anderson neither expressly nor inherently teaches a single medication of any kind, but instead merely states that the apparatus is used in the treatment of such diseases as Pulmonary Emphysema, Asthma, Bronchitis and other respiratory diseases (Abstract).

The Examiner asserts the argument that the limitation of claim 14 that, *the kit is for use in a per-hospital setting* is used in the preamble and has therefore not been given patentable weight. Appellant is not relaying on the limitations that *the kit is for use in a per-hospital setting* to distinguish over Anderson. However, the Examiner further reasons; "the system of Anderson is fully capable of delivering the medication as described." For the reasons stated above, Appellant disagrees. The apparatus of claims 7 and 14 does not deliver a medication.

With respect to claims 2-4, 6, 8 - 13, 17, 19, 21, 22 and 25 - 34, rejected under 35 U.S.C. 103(a), Appellant maintains that the Examiner has failed to establish *prima facie* obviousness because; all or the claim limitations are not taught or suggested by the prior art of record; because the teaching or suggestion to make the claimed combination and the reasonable expectation of success are not found in the prior art of record, but instead found in Appellant's disclosure; and, because none of the prior art references relied upon suggests the desirability of the combination.

In response thereto, the Examiner has presented the new argument that Anderson does not teach the structural limitations of an oxygen delivery system and a medication, because the limitation that the medication is for use in response to symptoms of an attack of vascular disease is functional language, and is not given any patentable weight. For the reasons stated above, Appellant disagrees with the Examiners new argument and further contends that the new argument applied by the Examiner constitutes new grounds for rejection.

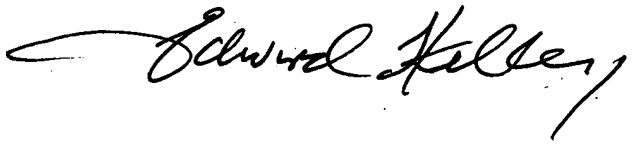
Appellant respectfully requests that any new grounds for rejection asserted in the Examiner's Answer not be considered on Appeal. Alternately, Appellant respectfully requests that the Examiner reopen prosecution on the merits in response to this Reply Brief to allow Appellant to properly address the new grounds for rejection asserted in the Examiner's Answer.

In addition, Appellant submits that the record is not clear that an appeal conference has been held because the Examiner's Answer is not signed by a supervisory examiner nor initialed by two appeal conference participants. Clarification in the record is hereby respectfully requested.

If the Examiner or the Board of Patent Judges feels that any further discussion of the invention would be helpful, appellant's representative is available by telephone at (781) 541-6579, by Fax at (781) 541-6747 or by email, kelley.ima@rcn.com, and earnestly solicits such discussion.

Respectively submitted,

Applicants



By: Edward L. Kelley Date: 4/23/04

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